JUN 22 2012

SECTION 2 – 510(k) SUMMARY

The 510(k) Summary is submitted in accordance with 21 CFR 807.92 and the requirements of the Safe Medical Device Act (SMDA) of 1990.

1. SUBMITTER'S NAME	Abbott Vascular
2. SUBMITTER'S ADDRESS	26531 Ynez Road, Temecula, CA 92591
3. TELEPHONE	(951) 914-3243
4. FAX	(951) 914-0339
5. CONTACT PERSON	Suzanne Redman
6. DATE PREPARED	April 20, 2011
7. DEVICE TRADE NAME	TREK™ OTW Coronary Dilatation Catheter MINI TREK™ OTW Coronary Dilatation Catheter
8. DEVICE COMMON NAME	• Coronary Dilatation Catheter • Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter
9. DEVICE CLASSIFICATION NAME	PTCA Catheter, LOX, Class II 21 CFR 870.5100
10. PREDICATE DEVICE NAME	TREK™ OTW Coronary Dilatation Catheter MINI TREK™ OTW Coronary Dilatation Catheter

11. DEVICE DESCRIPTION

The TREK OTW and MINI TREK OTW Coronary Dilatation Catheter are an over-the-wire co-axial design with a balloon at the distal tip. **Table 1** provides a matrix of the balloon diameters and lengths available.

Table 2-1 TREK OTW and MINI TREK OTW Size Matrix

Balloon Diameter (mm)	Balloon Length						
	6mm	8mm	12mm	15mm	20mm	25mm	30mm
MINI TREK OTW Coronary Dilatation Catheter							
1.20	X	X	X	X	X		
1.50	X	X	X	X	X		
2.00	X	X	X	X	X	X	X
TREK OTW Coronary Dilatation Catheter							
2.25	X	X	X	X	X	X	X
2.50	X	X	X	X	X	X	X
2.75	X	X	X	X	X	X	X
3.00	X	X	X	X	X	X	X
3.25	X	X	X	X	X	X	X
3.50	X	X	X	X	X	X	X
3.75	X	X	X	X	X	X	X
4.00	X	X	X	X	X	X	X
4.50			X	X			
5.00			X	X			

The balloon segment expands to a known diameter and length at a specific inflation pressure and has radiopaque marker(s) under the balloon to aid in positioning the balloon in a stenosis. The co-axial shaft consists of a tubular inner and outer member. The inner lumen permits the use of a guide wire to facilitate advancement of the catheter to and through the stenosis to be dilated. The outer lumen provides for inflation and deflation of the balloon with contrast fluid. Along the proximal portion of the shaft are brachial and femoral markers to aid in gauging the catheter's position relative to the guiding catheter tip when introducing the catheter through the guiding catheter. An adaption arm is located at the proximal end to provide access to the inflation lumen and guide wire lumen and allows connection with an inflation device.

12. INDICATIONS FOR USE

The TREK OTW and MINI TREK OTW Coronary Dilatation Catheters (1.50 mm – 5.00 mm) are indicated for:

a) balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion;

b) balloon dilatation of a coronary artery occlusion for the purpose of restoring coronary flow in patients with ST-segment elevation myocardial infarction;

c) balloon dilatation of a stent after implantation (balloon models 2.0 mm – 5.0 mm only).

The MINI TREK OTW 1.20 mm Coronary Dilatation Catheter is indicated for initial balloon dilatation of the stenotic portion of a coronary artery bypass graft stenosis (≥ 70% stenosis).

13. TECHNOLOGICAL CHARACTERISTICS

Comparisons of the new and predicate devices show that the technological characteristics such as product performance, design and intended use are substantially equivalent to the current marketed predicate devices.

14. PERFORMANCE DATA

The modified TREK OTW and MINI TREK OTW Coronary Dilatation Catheters were subjected to the following *in vitro* bench tests according to the requirements of *Guidance for Industry and FDA Staff – Class II Special Controls for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters*, September 8, 2010:

- Catheter Preparation
- Balloon Inflation / Balloon Deflation
- Catheter Shaft Fatigue
- Catheter Shaft Rupture
- Distal Catheter Tensile Strength
- Proximal Adaption Tensile Strength
- Inner Member Collapse
- Kink and Flexibility
- Torque

Biocompatibility testing previously conducted included cytotoxicity, sensitization, intracutaneous reactivity, acute systemic toxicity, hemolysis, pyrogen, and complement activation.

These *in vitro* bench and biocompatibility tests demonstrated that the TREK OTW and MINI TREK OTW Coronary Dilatation Catheters met all acceptance criteria and performed similarly to the predicate devices. No new safety or effectiveness issues were raised during the testing program and, therefore, these devices may be considered substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 22 2012

Abbott Vascular, Inc.
Ms. Suzanne Redman
Regulatory Affairs
26531 Ynez Road
Temecula, CA 92591

Re: K121222
Trade/Device Name: TREK OTW Coronary Dilatation Catheter and MINI TREK OTW Coronary Dilatation Catheter
Regulation Number: 21 CFR 870.5100
Regulation Name: PTCA Catheter
Regulatory Class: Class II
Product Code: LOX
Dated: May 23, 2012
Received: May 24, 2012

Dear Ms. Redman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 1 – INDICATIONS FOR USE

510(k) Number (if known): K121222

Device Names: TREK™ OTW Coronary Dilatation Catheter
MINI TREK™ OTW Coronary Dilatation Catheter

Indications for Use:

Balloon diameters 1.50 mm – 5.00 mm
The MINI TREK™ OTW and TREK™ OTW Coronary Dilatatoin Catheters are indicated for:
a) balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion;
b) balloon dilatation of a coronary artery occlusion for the purpose of restoring coronary flow in patients with ST-segment elevation myocardial infarction;
c) balloon dilatation of a stent after implantation (balloon models 2.0 mm – 5.0 mm only).

Balloon diameter 1.20 mm
The MINI TREK OTW 1.20 mm Coronary Dilatation Catheter is indicated for initial balloon dilatation of the stenotic portion of a coronary artery bypass stent graft (≥ 70% stenosis).

Prescription Use__X__ OR Over-The-Counter_____
(Per 21 CFR 801.109) (Optional Format 1-1-96)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K121222

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